Appl. No. 10/814,759
Docket No. 8482D
Amdt. dated 10/04/06
Reply to Office Action mailed on 07/03/06
Customer No. 27752

REMARKS

Claim Status

Claim 1 has been amended to specify the amount of sugar amine. Full support for this amendment is found on page 7, lines 8-10 of the specification. Claim 1 further has been amended to specify the amount of a vitamin B3 compound. Full support for this amendment is found on page 10, lines 18-19 of the specification.

Claim 2 has been amended to specify the amount of sugar amine. Full support for this amendment similarly is found on page 7, lines 8 – 10 of the specification.

Claim 3 has been amended to reflect a different range of percentages of the vitamin B3 compound. Full support for this amendment is found on page 10, lines 18-19 of the specification.

Claim 5 has been canceled without prejudice.

Claim 6 has been amended to depend from claim 1.

Claim 10 has been amended to include specific retinoid compounds. Full support for this amendment is found on page 8, line 33 to page 9, line 2 of the specification.

Claim 13 has been amended to specify ascorbic acid, its salts, and magnesium ascorbyl phosphate. Full support for this amendment is found on page 29, line 25, and in the originally submitted claims.

Claim 16 has been canceled without prejudice.

Rejection Under 35 USC §112, First Paragraph

The Office Action rejects claim 17 under 35 U.S.C. 112, first paragraph, stating that the specification fails to enable "regulating the condition of skin." Applicants respectfully traverse.

The Office Action states that the skilled artisan would view that the recitation "regulating the condition of skin" would reasonably encompass both enhancing and reducing the tactile discontinuities of skin. Applicants fail to understand the basis for this statement.

With respect to claim interpretation, the Federal Circuit Court of Appeals recently has reiterated "we look to the specification to ascertain the meaning of a claim term as it is used by

the inventor in the context of the entirety of his invention." *Phillips v. AWH Corp.*, 363 F.3d 1207, 1213 (Fed. Cir. 2005). The specification states on page 5, line 32: "'regulating skin condition' includes prophylactically regulating and/or therapeutically regulating skin condition, and may involve *one or more* of the following benefits (emphasis added)." The specification clearly exemplifies the benefits associated with regulating skin condition, including increasing the convolution of the dermal-epidermal border (p. 6, line 1, see also explanation of convolution of the dermal-epidermal border - not to be confused with the outer layer of the skin - on page 2, lines 3 – 8), and preventing loss of skin elasticity (p. 6, line 2). The specification clearly defines prophylactically regulating skin condition (p. 6, lines 7-8), and therapeutically regulating skin condition (p. 6, lines 10-11). Nowhere does the specification state that regulating the condition of skin includes *decreasing* the convolution of the dermal-epidermal border or *decreasing* the firmness of skin or *increasing* the tactile discontinuities of the skin, none of which would be considered a benefit. Therefore, the Office Action appears to lack basis for the assertion for how a skilled artisan would view the term "regulating skin condition," given that the term is clearly defined and exemplified in the specification, and in light of well-established case law that the specification defines the scope of the claims.

The Office Action further states that the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Applicants respectfully traverse this assertion and refer to page 43, lines 8-30 of the specification in which is set forth with particularity how the invention may be practiced.

The Office Action states "the skilled artisan would view that regulating the tactile discontinuities in the skin...are highly unlikely." Applicants respectfully traverse this assertion on the basis of the arguments presented above. Applicants further request clarification of the assertion that "increasing and decreasing the wrinkles in the skin are highly unlikely," as the specification does not include "increasing the wrinkles in the skin" in the definition of regulating skin condition. In fact, the specification clearly states that the claimed composition provides one or more skin *benefits*. It would not appear that one of skill in the art would consider decreasing the convolution of the dermal-epidermal border or increasing tactile discontinuities, such as wrinkles and lines, a skin benefit.

The Office Action states that the skilled artisan would view that regulating, encompassing both increasing and decreasing, the firmness, tone, or texture of skin of a subject, or wrinkles in skin of a subject, is highly unpredictable, since the skilled artisan would not understand how the same compound or agent could increase and decrease the firmness, tone, or texture of skin of a subject or wrinkles in the skin of a subject. Applicants traverse on the basis of the arguments

above, and point out the specification does not state that the same compound would both increase *and* decrease the same effect, in particular when no benefit to the skin, as defined by the Applicants, is provided.

The Office Action states that in the instant case, no working examples are presented showing how to use the composition to regulate the many conditions of skin, or how to prevent, retard, arrest or reverse the tactile discontinuities or wrinkles in the skin. Applicants respectfully refer to Examples I-XI on pages 44-46 of the specification, which enable one of skill in the art to make the compositions, and to page 43, lines 8 – 30, which explain how to use the composition, and in particular, line 8 which states "Regulating keratinous tissue condition is preferably practiced by applying a composition ..." Applicants again reiterate that regulating keratinous tissue is clearly defined and exemplified on pages 7 – 8 of the specification.

The Office Action concludes that to practice the claimed invention, a person of skill in the art would have to engage in undue experimentation to achieve methods of regulating the condition of skin. Applicants respectfully traverse, and assert that because the examples clearly explain how to make several embodiments of the present invention, and because the specification clearly explains how to use the compositions, little or no experimentation is necessary to achieve regulation of the condition of skin *as defined by Applicants.*

On the basis of the above, Applicants respectfully request that the rejection under 35 USC 112, first paragraph be withdrawn, and alternatively, that further clarification of the basis for this rejection be provided.

Rejection Under 35 USC §112, Second Paragraph

The Office Action rejects claim 1 under 35 USC §112, second paragraph, asserting that the term "safe and effective" would not enable one of skill in the art to ascertain the scope of the invention. Applicants have amended instant claim 1 to replace this term with a range of percentages. Applicants believe that with this amendment, this rejection is overcome.

The Office Action rejects claim 10 under 35 USC §112, second paragraph, asserting that the term "retinoids" is indefinite. Applicants have amended claim 10 and replaced the term "retinoids" with specific retinoid compounds, which Applicants believe enable one of skill in the art to more clearly ascertain the scope of the claim.

The Office Action rejects claims 5, 11, 13, and 16 under 35 USC §112, second paragraph, asserting that the term "derivative" renders the claims indefinite. Applicants have

amended claims 13 to delete reference to "derivatives," and claims 5 and 16 have been canceled without prejudice. With respect to claim 11, Applicants assert that the term "palmitoyl peptide derivatives" is sufficiently defined as "palmitoyl" is readily understood by one of skill in the art to mean a C16 derivative. Furthermore, palmitoyl derivative peptides are exemplified on page 10, lines 4 – 9, both by sequence and by tradename. Applicants therefore respectfully assert that this term does not refer to such a widely varying group as to render the term indefinite.

On the basis of the above, Applicants respectfully request that all rejections under 35 USC §112, second paragraph, be withdrawn.

Rejection Under 35 USC §102 Over U.S. 5,804,594

The Office Action rejects original claims 1-10, 12-15, and 17 as anticipated by Murad et al., U.S. Patent No. 5,804, 594, ("Murad"). Applicants respectfully traverse.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053. A rejection based on 35 U.S.C 102(a) or (b) may be overcome by amending the claims to patentably distinguish the present invention over the prior art. M.P.E.P. 706.02(b)-(c).

The Office Action states that Murad discloses the use of 17.1% N-acetylglucosamine. Applicants have amended claims to comprise from about 0.001% to about 4% of a sugar amine. Therefore, Murad fails to set forth each and every element of the amended claims. On this basis, applicants respectfully request that this rejection be withdrawn.

Rejection Under 35 USC §103(a) Over U.S. 5,804,594 in view of U.S. 5,935,556.

The Office Action rejects original claims 11 and 16 under 35 U.S.C. §103(a) over Murad in view of Tanner et al., U.S. Patent No. 5,935,556 ("Tanner"). Applicants respectfully traverse.

According to *In re Vaeck*, 20 USPQ2d 1438:

> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Applicants assert that the Office Action has failed to establish a *prima facie* case of obviousness, as there is no suggestion or motivation to combine the references, and that the combination of references fails to teach all limitations of the amended claims.

Murad teaches pharmaceutical compositions and a method of improving skin, preferably by oral ingestion of a composition comprising a sugar compound. Murad teaches that the composition comprises from about 5% to about 50% of the sugar compound. Applicants have amended the instant claims to comprise from about 0.001% to about 4% of a sugar amine. Therefore, Murad does not teach all limitations of the amended claims. Nor does Murad suggest a percentage of a sugar compound near the claimed range. The reference exemplifies oral compositions (tablets) comprising 17.1% N-acetylglucosamine, well above the instantly claimed range. There is no teaching or even suggestion that a lower percentage of a sugar amine would be effective to impart a skin benefit when topically applied to the skin.

The Office Action states that Murad teaches topical administration, however there is no teaching that Applicants' claimed percentages of sugar amine would be desirable or effective for topical application. There is further no teaching of a dermatologically-acceptable carrier for the sugar amine and vitamin B3 compound. Whereas the Office Action states that coconut oil is a dermatologically-acceptable carrier, the exemplified 0.1% coconut oil present in the tablet does not suggest that this would be a dermatologically-acceptable carrier, as claimed by Applicants. Applicants define dermatologically-acceptable as "suitable for topical application to the keratinous tissue, has good aesthetic properties, [and] is compatible with the actives of the present invention..." (specification, p. 13, line 15). There is no indication that coconut oil, in particular in the disclosed amount, would satisfy the instant claim limitations.

Tanner fails to teach or suggest the use of a sugar amine to regulate the condition of skin.

Because the combination of references fails to teach or suggest all the claim limitations of amended claim 1, and because there is no suggestion or motivation to combine the references, the Office Action has failed to establish a *prima facie* case of obviousness of instant claim 1 and of claim 11, which ultimately depends from claim 1. Claim 16 has been canceled without prejudice. Applicants therefore respectfully request that this rejection be withdrawn.

Conclusion

Applicants thank the Examiner for the thorough and careful examination of this application. This response represents an earnest effort to place the application in proper form and

to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-4, 6-15, and 17 is requested.

Respectfully submitted,

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